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In the Supreme Court of the United States

OCTOBER TERM, 1967

AMP INCORPORATED, PETITIONER

v.

WILBUR J. COHEN, SECRETARY OF HEALTH, EDUCATION, AND WELFARE; AND JAMES L. GODDARD, COMMISSIONER OF FOOD AND DRUGS

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 13a-25a) is reported at 389 F.2d 825.

JURISDICTION

The judgment of the court of appeals was entered on February 13, 1968. The petition for a writ of certiorari was filed May 10, 1968. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether articles containing a strand of nylon suture, manufactured for use in ligating blood vessels of humans as a part of a surgical procedure, are drugs as defined by the Federal Food, Drug, and Cosmetic Act.

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938), as amended, 21 U.S.C. 301, *et seq.*, provides in part:

> Sec. 201 [21 U.S.C. (Supp. II) 321]. For the purposes of this Act—
>
> * * * *
>
> (g) (1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C); but does not include devices or their components, parts, or accessories.
>
> * * * *
>
> (h) The term "device" * * * means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation,

treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, * * *; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Sec. 505 [21 U.S.C. 355]. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufac-

ture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

* * * *

STATEMENT

Petitioner manufactures two different articles, both of which are made of plastic and are intended for use in tying off (ligating) blood vessels which are severed during surgery. Each article is used as a means of applying nylon suture material in a loop around the severed blood vessel, tightening the loop and locking it in such a fashion as to constrict the flow of blood (J.A. 6a-12a, Ex. F). Specimens are physically attached to the petition.

One article consists of a thin hollow plastic tube from which the nylon suture material extends and is fastened in a loop by means of a tiny disc. The tube is inserted into the opening in the human body occasioned by the surgery, the loop is placed around the bleeding vessel, is drawn tight and locked by means of the disc. The other article is a plastic hemostat to which the suture material is attached in the form of a loop. The hemostat is used in the cavity of the operation to apply the looped suture material which is pulled tight and fastened by means of the locking disc. The plastic tube and hemostat function as applicators in which the nylon suture material is packed and are used to apply the ligator (J.A. 46a).

In each instance the excess nylon suture thread is cut off from that used to ligate the blood vessel. The ligating thread and locking disc remain permanently in the body of the patient. The plastic applicators and excess suture thread are discarded. The nylon suture material is recognized in the United States Pharmacopoeia (J.A. 34a; 38a-42a, Ex. A).

Petitioner's articles introduce into surgical practice an entirely new method of ligating severed blood vessels. The conventional and accepted method is for the surgeon to hand-tie ligatures by means of a surgeon's knot (J.A. 50a). Petitioner's products constitute a unique method of administration of the ligature which is not recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and efficacy of such drugs for use in ligating bleeding vessels during surgery (J.A. 35a, 46a).

In response to its inquiry, petitioner was advised in early 1966 by the Food and Drug Administration that it regarded the above-described articles as "new drugs" and that a new drug application must be submitted and approved before the articles could be marketed. Thereafter, on May 4, 1966, petitioner filed a "Notice of Claimed Investigational Exemption" pursuant to the requirements of the Act, and conducted clinical investigations of its product (J.A. 45a, 49a-51a).

In November 1966, Doctors Gyarfas and Casola, of the Division of Dental and Surgical Adjuncts of the Food and Drug Administration, informed petitioner of various deficiencies in its Investigational Drug Ap-

plication. They also stated that the Food and Drug Administration would require long-term studies concerning the possible cancer-producing effects of the implanted ligature loop and nylon button (J.A. 37a).

In January 1967, petitioner withdrew its "Notice of Claimed Investigational Exemption" and advised the Food and Drug Administration that it took the position that the articles were not "drugs" but "devices." Petitioner stated that it had concluded the product was safe and effective for its intended use. Thereafter, petitioner proceeded to comply with the requirements of the Act relating to devices. It was advised that the Food and Drug Administration considered the articles to be "new drugs" and that distribution in interstate commerce otherwise than in compliance with the Investigational New Drug Regulations might result in proceedings against petitioner or its products (J.A. 37a).

Petitioner thereupon filed an action in the United States District Court for the Southern District of New York requesting a declaratory judgment that the articles are devices. It also sought an injunction restraining the enforcement of the new drug provisions of the Act. Both parties moved for summary judgment.

On September 29, 1967, the district court granted respondents' motion holding that the products are "new drugs" within the meaning of the Act (Pet. App. 2a-12a). The court of appeals affirmed (Pet. App. 13a-25a).

ARGUMENT

1. The decision below is correct. Petitioner's products were properly held to fall within the statutory definition of "drug" rather than that of "device". Their purpose is to facilitate the administration of their principal element in the human body. The essential element, nylon suture material, is recognized as a drug in the official United States Pharmacopoeia and therefore is squarely within that portion of the statutory definition which defines as drugs "articles recognized in the Official United States Pharmacopoeia." Cf. *United States* v. *48 Dozen Packages * * * of Gauze Bandage*, 94 F.2d 641 (C.A. 2). Moreover, the end use of the suture material is to ligate, or tie off, bleeding vessels during the performance of surgical operations. Since it is used to affect the structure and function of the body during the course of medical treatment performed either to cure, mitigate, or prevent diseases in humans, the use of the essential element places the articles within the second and third categories of "drugs" found in the statutory definition.

Inasmuch as the principal element of the products is an article which will be permanently incorporated into human body structure and which will have an effect upon it by prevention of internal bleeding, the products possess functional qualities not usually found in purely mechanical devices. The fact that the essential element is attached to a plastic hemostat or is within a thin plastic tube and is fashioned in a noose with a special locking disc does not change it into an

"instrument, contrivance or apparatus" in the sense intended by Congress in defining a "device."

Classification of these articles as drugs is in accord with the underlying reasons for requiring pre-market clearance of new drugs. The method of packaging subjects the products to the hazard of breakage of the plastic containers or leakage of the seals. The articles are not of a character to be re-sterilized by usual methods available in hospitals (J.A. 19a). Even more important is the fact that the locking button is implanted in the body. It is not known whether it may slip or loosen, thus causing internal bleeding, or whether its presence will, over a period of time, produce irritation or cause a carcinogenic (cancer-producing) reaction (J.A. 35a-36a). It was to ascertain the existence or extent of such possible dangers which might arise from the uses of drugs in humans that Congress adopted the pre-market clearance requirements found in Section 505 of the Act (21 U.S.C. 355).

2. The decision below does not, as petitioner contends, conflict with that of the Court of Appeals for the Sixth Circuit in *United States* v. *An Article of Drug* * * * *Bacto-Unidisk* * * *, No. 17592, decided March 29, 1968 (Pet. App. 27-31). That case involved discs impregnated with antibiotic drugs which were used to test the reaction of a specimen drawn from a patient. The court held that the discs were not a drug subject to batch testing because they were not "articles administered to man or other animals, either internally or externally" (Pet. App. 30a). Thus, whether or not the Sixth Circuit decision is cor-

rect, the case differs from the present one both factually and legally. In this case the article is used in the course of a surgical operation to facilitate the administration of suture material which remains in the human body. Both the suture material and the applicators enter the wound caused by the surgical incision, and the suture material is permanently affixed to the human body.

3. The question involved here does not have the broad implications which petitioner endeavors to assign to it. There is nothing new in the legal principle that the Act, being intended to protect the public health, should be given a liberal construction consistent with consumer protection. *Kordel* v. *United States*, 335 U.S. 345; *United States* v. *Urbuteit*, 335 U.S. 355; *Pasadena Research Laboratories* v. *United States*, 169 F.2d 375 (C.A. 9), certiorari denied, 335 U.S. 853; *United States* v. *"Cal's Tupelo Blossom U.S. Fancy Pure Honey"*, 344 F.2d 288 (C.A. 6); see *United States* v. *Dotterweich*, 320 U.S. 277. Whether, in the light of that principle, a particular article may or may not be classified as a drug within the intendment of the Act depends upon the factual particularities of its intended use. The decision below properly considers the articles here involved to be intended for a use contemplated by the statute as requiring the regulatory safeguards specified for "drugs".

CONCLUSION

For the reasons stated, it is respectfully submitted that the petition for a writ of certiorari should be denied.

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